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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,149	11/17/2003	Robert H. Getzenberg	076333-0331	9439

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EXAMINER	
REDDIG, PETER J	
ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,149	GETZENBERG, ROBERT H.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *2-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed April 4, 2007 in response to the Office Action of January 4, 2007 is acknowledged and has been entered. Claim 1 has been amended and new claims 17-24 have been added. Claims 2-16 have been previously withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

2. Claims 1 and 17-24 are currently being examined.

3. The following rejections/objections are being maintained:

Priority

4. Applicants argue that the present claims are entitled to the benefit of the earliest application to which priority is claimed, U.S. provisional application no. 60/041,860, filed April 8, 1997. Table 2 on page 26, lines 20-27 of the '860 application explicitly recite the molecular weights recited in claim 1. While the header of Table 2 states that the units are in "kD," one of skill in the art would readily recognize this is a typographical error. Applicants are correcting that typographical error presently, as indicated above. Accordingly, the present claims are entitled to the benefit of the '860 application, because the '860 application recites the same molecular weights as the present claims.

Applicants arguments have been carefully, considered but have not been found persuasive. Although one of skill in the art would recognize the typographical error of "kD", the instant claims are drawn to an isolated antibody directed against nuclear matrix proteins of *about* a certain molecular weight and pI and support for this claimed genus of proteins is not found in the parent applications. Thus the priority date remains 11/17/2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 remains rejected and claims 17-24 are rejected under 35 USC 112 2nd para. for the reasons previously set forth in section 12 of the Office Action of January 4, 2007.

Applicant argues that the MPEP makes clear that the "fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph." MPEP § 2173.05(b). A claim is not considered indefinite when one of skill in the art "would be ... reasonably apprised of the scope of the invention." Id. In the particular case of the use of "about," court's have routinely that its use does not render a claim indefinite. See Ex parte Eastwood, 163 USPQ 316 (Bd. App. 1968);W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). When court's have found a claim indefinite for use of "about," there is often prior art which cannot be distinguished because of the use of "about."

Applicant argues that the here, one of skill in the art would be readily apprised of the metes and bounds of claim 1. It is commonly understood that molecular weights and isoelectric points can vary slightly depending on particular test conditions. Thus, one of skill in the art expects slight variations in these values. In addition, the proteins are defined by two separate numerical values, molecular weight and isoelectric point, so the proteins are not defined by only a single characteristic that is modified by "about." Applicants argue that the case law rejecting the use of "about" does not apply, because there is not prior art of record that teaches proteins with properties similar to those recited by the claims. Thus, one of skill in the art would be readily able to distinguish the recited proteins from the proteins known in the art.

Applicant's arguments have been carefully considered, but have not been found persuasive. Although the courts have frequently found "about" not to be indefinite in particular

cases, given the proximity of MWs and pIs for the claimed proteins, given that the preposition "about" leads to overlapping MW and pIs ranges for the claimed proteins, and given, as Applicants have stated on the record, that molecular weights and isoelectric points can vary slightly depending on particular test conditions, the claims are indefinite because it cannot be determined if the same proteins or different proteins are being claimed in cases in which the ranges would be reasonably be expected to overlap such as for the proteins claimed in 1b-e and claims 18-21, as previously set forth.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 remains rejected and claims 17-24 are rejected under 35 USC 112 1st para. as lacking an adequate written description for the reasons previously set forth in section 15 of the Office Action of January 4, 2007.

Applicants argue that as discussed above in Section VII, the specification contains an extensive description of the recited proteins. This description includes a description of how to obtain the proteins and how the molecular weights and isoelectric points can be determined. Such a description is sufficient to demonstrate possession of the recited proteins to one of skill in the art. The Office Action cites University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002) as support for its argument that the claims lack written description support. Applicants argue that these cases do not support the Office Action's position.

Applicant argues that first, Lilly and Enzo are factually different from the present case. In both Lilly and Enzo, the patentee was attempting to claim more than it actually possessed. More specifically, the patentee in Lilly was attempting to claim, inter alia, "vertebrate insulin cDNA," although it had not isolated all "vertebrate insulin cDNA." Similarly, the Enzo patentee was attempting to claim probes by binding ability alone. While it had obtained some probes with the recited binding, it was attempting to claim all probes with the recited binding. Here, Applicants are not attempting to claim more than what they possessed. Specifically, claim 1 recites only proteins that Applicants isolated and characterized, as demonstrated in Table 2. On this basis, the present claims are distinguishable from the claims at issue in Lilly and Enzo. Thus, Lilly and Enzo do not lead to the conclusion that the present claims lack written description support.

Applicant's arguments have been carefully considered, but have not been found persuasive. Applicants are claiming more than they posses. Claim 1 and claims 17-24 do not simply claim the proteins that Applicant has isolated and characterized, but they include a larger genus of proteins to which the claimed antibodies will bind. The larger genus of proteins is encompassed by the claims because of the presence of "about" and, as Applicants have stated on the record, that molecular weights and isoelectric points can vary slightly depending on particular test conditions. Thus the claims encompass proteins, and antibodies to said proteins, which do not have the same MW and pI of those isolated by Applicants.

Applicant argues that second, and related to the first point, Lilly and Enzo are distinguishable from the present case in the legal question they addressed. Lilly and Enzo both addressed written description support for a genus in which the specification listed only specific species of the genus. Here, the claims are not directed to a genus of proteins. Instead, the claims

recite only five specific proteins, each of which was isolated and characterized as described in the specification. Thus, the present claims do not raise the same legal issues as in Lilly and Enzo.

Applicant's arguments have been carefully considered, but have not been found persuasive. As set forth above, Applicant is claiming a genus of proteins for each protein in claim 1a-e and in claim 17-24. Thus, Applicant has only recited one species of protein for each genus of proteins claimed in claim 1 a-e and claims 17-24 and thus the teachings of the specification are not sufficiently representative of the genus claimed to meet the requirements of the written description as set forth in Lilly.

Applicant argues that third, even if the Lilly and Enzo were applied to the claims as suggested by the Office Action, the result would still be that the claims possess written description support. The Federal Circuit stated in Lilly that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." Lilly, 119 F.3d at 1567 (emphasis added). Thus, the written description must be "sufficient to distinguish it from other materials." Here, the specification describes the proteins in terms of isoelectric point, molecular weight, and their presence in cancerous renal cells but not normal renal cells. This description is sufficient to distinguish the recited proteins "from other materials." The Federal Circuit in Enzo stated that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of

such characteristics." Enzo, 296 F.3d at 1324 (emphasis omitted, bracketed material in original). Thus, Enzo requires a showing that the "invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics." Those "identifying characteristics" can include "physical and/or chemical properties" and "functional characteristics." Here, the recited proteins are describes in terms of a number of identifying characteristics, as discussed above. These characteristics include the physical characteristics of molecular weight and isoelectric point. In addition, the proteins are present in cancerous renal cells but not normal renal cells. Such a description shows that the "invention [was] complete."

Applicant's arguments have been carefully considered, but have not been found persuasive. The larger genus of proteins encompassed by Claim 1 and claims 17-24 have distinct physical and/or chemical properties, i.e. because of the presence of "about" and, as Applicant has stated on the record, that molecular weights and isoelectric points can vary slightly depending on particular test conditions. Thus the claims encompass proteins, and antibodies to said proteins, which do not have the same MW and pI of those isolated by Applicants and thus the single species of each RCCA protein identified does not provide a written description for the genus of proteins encompassed by the claims for each RCCA protein.

Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 1 remains rejected and claims 17-21 are rejected under 35 USC 103 for the reasons previously set forth in section 16 of the Office Action of January 4, 2007.

Applicants argue that Konety is not prior art to claim 1. The rejection is premised on the determination that the claim 1 entitled to a priority date of November 17, 2003. However, as discussed in Section II, claim 1 is entitled to the benefit of the earliest application to which priority is claimed, U.S. provisional application no. 60/041,860, filed April 8, 1997. Because the present claims are entitled to a priority date no later than April 8, 1997, Konety is not prior art.

Applicant's arguments have been considered, but have not been found persuasive because the priority remains November 17, 2003 for the reasons set forth above and no other arguments have been presented as to the validity of the previous rejection.

Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 17-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Getzenberg (WO98/45432, October 15, 1998).

1. An isolated antibody directed against a nuclear matrix protein in a human subject, wherein said protein is absent in normal renal cells but present in cancerous renal cells and is selected from the group consisting of: (a) RCCA-1 having a molecular weight of about 53 kD and a pI of about 9.30; (b) RCCA-2 having a molecular weight of about 32 kD and a pI of about 6.95; (c) RCCA-3 having a molecular weight of about 27 kD and a pI of about 6.50; (d) RCCA-4 having a molecular weight of about 20 kD and a pI of about 5.25; and (e) RCCA-5 having a molecular weight of about 15kD and a pI of about 6.00.

17. The isolated antibody of claim 1, wherein the antibody is against RCCA-1 having a molecular weight of about 53 kD and a pI of about 9.30.

18. The isolated antibody of claim 1, wherein the antibody is against RCCA-2 having a molecular weight of about 32 kD and a pI of about 6.95.

19. The isolated antibody of claim 1, wherein the antibody is against RCCA-3 having a molecular weight of about 27 kD and a pI of about 6.50.

20. The isolated antibody of claim 1, wherein the antibody is against RCCA-4 having a molecular weight of about 20 kD and a pI of about 5.25.

21. The isolated antibody of claim 1, wherein the antibody is against RCCA-5 having a molecular weight of about 15 kD and a pI of about 6.00.

22. The isolated antibody of claim 1, wherein the antibody is a polyclonal antibody.

23. The isolated antibody of claim 1, wherein the antibody is a monoclonal antibody.

24. The isolated antibody of claim 1, wherein the antibody is detectably labeled.

Getzenberg et al. teach (a) RCCA-1 having a molecular weight of 53,000 kD and a pI of 9.30; (b) RCCA-2 having a molecular weight of 32,000 kD and a pI of 6.95; (c) RCCA-3 having a molecular weight of 27,000 kD and a pI of 6.50; (d) RCCA-4 having a molecular weight of 20,000 kD and a pI of 5.25; and (e) RCCA-5 having a molecular weight of 15,000 kD and a pI of 6.00 which are present only in human renal cell carcinoma tumor samples and were absent in all normal kidney tissue, see Table 2, p. 26 left column.

Getzenberg et al teach an antibody to RCCA 1-5, see claim 32. Getzenberg et al. teach purification of the RCCA proteins with polyclonal and monoclonal antibodies to the proteins of the invention, see p. 5, lines 20-26 and claim 33. Getzenberg et al. teach labeling monoclonal antibodies to the proteins of the invention for immunoassays, see p.11 and claim 27.

Given that the prior art reference is authored by the inventor of the instant application, given that the Applicants have clarified the record as to the MW of the proteins of the instant invention, the product of the prior art comprises the same product as claimed in the instant invention, that is purified antibodies to the RCCA 1-5 proteins, thus the claimed products are anticipated because the product will inherently be an antibodies to the RCCA 1-5 proteins of the instant invention. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Although the reference does not specifically state that the RCCA 1-5 proteins have the same MW of the instant invention, the claimed product appears to be the same as the prior art product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed method is

different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA)

9. All other objections and rejections recited in Office Action of January 4, 2007 are withdrawn.

10. No claims allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0890. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

PJR